

LABEL IN PART: (Vial and carton) "10 cc Multiple Dose Sterile Vial Cardiobee 15 Injection Each cc contains 100 mg. of Na-Glucono-di (N-Diisopropylamino) Acetate, Benzyl Alcohol 2% Physiological Saline Solution q.s. For Veterinary Use Only Dist. by Zirin Enterprises Hialeah, Florida" and (vial) "Blue * * * Gold B-15 Capsules each capsule contains 50 mg. Pangamic Acid (Vitamin B-15) Na-Glucono-di (N-diisopropylamino) acetate."

LIBELED: 12-4-58, S. Dist. Fla.

CHARGE: 505(a)—the articles were new drugs which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drugs.

DISPOSITION: 8-4-59. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5986. Pituitary anterior solution. (F.D.C. No. 42984. S. No. 28-499 P.)

QUANTITY: 75 ctnd. vials at Houston, Tex.

SHIPPED: 1-27-59, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Vial and ctn.) "30 cc. Multiple Dose Vial Vitopit * * * Intramuscular Only * * * Distributed by Coastal Medical Supply Co. Houston, Texas Each cc. Represents The Water Soluble Extraction of Dried Glands Derived From: Anterior Pituitary, Fresh Gland * * * 10½ Grs. Ovarian Whole Gland, Fresh Gland * * * 40 Grs. Procaine HCL * * * 1% Chlorobutanol (Chloral Deriv.) 0.5% Contains No Recognized Therapeutically Active Ingredients. Indications: Non-Specific Protein Therapy."

LIBELED: 4-15-59, S. Dist. Tex.

CHARGE: 502(a)—when shipped, the label statement "Indications: Non-specific Protein Therapy" was false and misleading as applied to an article which is not an adequate and effective protein therapy treatment; and 502(f) (1)—the label of the article failed to bear adequate directions for use since no adequate directions could be written as the article was without therapeutic value.

DISPOSITION: 6-1-59. Default—destruction.

5987. Nutri-Bio Food Supplement. (F.D.C. No. 43216. S. No. 51-962 P.)

INFORMATION FILED: 8-5-59, Dist. Minn., against Gordon R. Cook, t/a Nutri-Bio Products, Brainerd, Minn.

ALLEGED VIOLATION: On 2-16-59, while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant caused oral representations to be made in the course of a sales talk holding the article out as an effective treatment for various diseases, symptoms, and conditions as hereinafter described, which act resulted in the article being misbranded.

LABEL IN PART: (Ctn.) "NUTRI-BIO food supplement natural or organic VITAMINS AND MINERALS Suggested Daily Portions As a Dietary Supplement 364 Mineral Tablets 182 Vitamin Tablets."

CHARGE: 502(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, sinusitis, nervous indigestion, arthritis, swelling of joints, rheumatism, reducing, overeating, hunger, gaining weight, nervousness, nervous breakdown, inadequate assimilation of food, blood clot, cavities in teeth, diarrhea of infants, ulcers, stomach flu, lack of

balance of the stomach, gallstones, kidney stones, bleeding ulcers, balancing the acids of the stomach, irritation of the stomach, tiredness, rundown condition, colds and other respiratory ailments, heart attacks, heart trouble, strokes, hardening of the arteries, and improper circulation of the blood, which were the diseases, symptoms, and conditions for which the article was held out by the defendant in the course of the above-mentioned sales talk.

PLEA: Guilty.

DISPOSITION: 9-4-59. The defendant was sentenced to the custody of the United States Marshal for one hour and fined \$100.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5988. Methrodyne tablets. (F.D.C. No. 42859. S. No. 47-822 P.)

QUANTITY: 84 ctns., 12 btl. each, and 9 btl., at Hartford, Conn.

SHIPPED: In 1952, from Newark, N.J., by Chase Chemical Co.

LABEL IN PART: (Btl.) "Metrodyne * * * Anodyne-Antipyretic Distributed by Metro Products, Inc., Hartford, Connecticut * * * Each tablet contains: Acetylsalicylic Acid 3 grains Acetophenetidin 2 grains Aluminum Hydroxide, Magnesium Carbonate present as buffer substances."

RESULTS OF INVESTIGATION: Examination showed that each tablet of the article contained 55 percent of the labeled amount of aspirin (acetylsalicylic acid) and the aspirin in the article was undergoing decomposition.

LIBELED: 3-12-59, Dist. Conn.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it was represented to possess; and 502(a)—the label statement "Each Tablet Contains * * * Acetylsalicylic Acid 3 grains" was false and misleading as applied to a product which contained less than 3 grains of aspirin; and 502(a)—when shipped, the label statement "To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product not restricted to prescription sale; and 502(e) (2)—the label of the article failed to bear the common or usual name of the active ingredient, aspirin.

DISPOSITION: 6-20-59. Default—destruction.

5989. HOC Hangover capsules. (F.D.C. No. 43307. S. No. 53-546 P.)

QUANTITY: 1 drum of 20,000 capsules, and 1,600 plastic boxes, 3 capsules each, at Los Angeles, Calif., in possession of HOC Laboratories, Inc.

SHIPPED: The article was shipped in bulk, between 5-5-59 and 5-20-59, from Inwood, Long Island, N.Y.

LABEL IN PART: (Drum insert label) "Kuvet Capsule Formula * * * Each Capsule Contains: * * * Yeast Protein Enzymatic Hydrolysate 2 gr. Alfalfa Lvs. Po. 2 gr. Vitamin B-1 (Thiamin Chloride) 1 mg. * * * Vitamin B-2 (Riboflavin) 1.5 mg. * * * Ascorbic Acid (as sodium ascorbate) 30 mg. Magnesium Trisilicate 3 gr. Chlorophyllins 5 mg."; (insert label of boxes) "A Product of HOC Laboratories, Inc., Los Angeles, Calif. HOC Hang-Over Capsules Directions and Ingredients: Each Capsule Contains: (a) Vitamin B₁ (Thiamine HCl) 100% minimum adult daily requirement Vitamin B₂ Riboflavin) 125% minimum adult daily requirement Vitamin C (Ascorbic Acid) 100% minimum adult daily requirement A scientific blended base of High Potency Yeast Protein Enzymatic Hydrolysate, Alfalfa and Chlorophyllins."

ACCOMPANYING LABELING: Display cards for retail packages bearing the words "H.O.C. Capsules Overindulgence," and a number of loose box labels.